## II. SUMMARY AND CERTIFICATION

### A. 510(k) Summary

OCT 5 2012

**Submitter:** SterilMed, Inc.

**Contact Person:** Jason Skramsted
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Maple Grove, MN 55369
Phone: 763-488-3483
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**Date Prepared:** 04 January 2012

**Trade Name:** Reprocessed Surgical Electric Instrument

**Classification Name:** Electrosurgical Cutting and Coagulation Device and Accessories, Reprocessed

**Classification Number:** Class II, 21 CFR 878.4400

**Product Code:** NUJ

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|---|---|
| **Predicate Devices:** | The reprocessed sealer/divider is substantially equivalent to the Covidien LigaSure Impact™ Hand Activated Sealer/Divider (K070162). |
| **Device Description:** | The sealer/divider is for use in open surgical procedures to seal vessels up to and including 7 mm, lymphatics, and tissue bundles. The sealer/divider can be used to seal pulmonary vasculature when used with the ForceTriad™ energy platform.<br>The sealer/divider has an 18 cm shaft with a 13.5 mm diameter and can be rotated 180 degrees. The curved jaw is 36 mm long with a 34 mm cutting length. The sealer/divider is activated by pulling the handle until latched and pressing the button on the device or depressing the foot switch. |
| **Intended Use:** | The Reprocessed Surgical Electric Instrument (hereinafter sealer/divider) is indicated for use in open surgical procedures to seal vessels up to and including 7 mm, lymphatics, and tissue bundles. When used with the ForceTriad™ energy platform the sealer/divider can also be used to seal pulmonary vasculature. The sealer/divider should not be used for tubal sterilization or tubal coagulation as it has not been shown effective for sterilization procedures. |
| **Technological Characteristics:** | The reprocessed surgical electric instruments are identical to the predicate devices in design, materials of construction, and intended use. There are no changes to the clinical applications, patient population, performance specifications, or method of operation. |
| **Functional and Safety Testing:** | Representative samples of reprocessed sealer/dividers were tested to demonstrate appropriate functional characteristics. Process validation testing was performed to validate the cleaning and sterilization procedures as well as device packaging. In addition, the manufacturing process includes visual and validated functional testing of all products produced. |
| **Summary of Non-clinical Tests Conducted:** | Specific non-clinical tests performed included: cleaning validation, sterilization validation (ISO 11135, USP <71>), biocompatibility testing (ISO 10993-1), ethylene oxide residual testing (ISO 10993-7), packaging validation (ASTM D4169, ASTM F88, ASTM F1929, ASTM F2096), and shelf life validation (ASTM 1980-07). In addition, validation of functional performance (bench testing) was performed through simulated use on beef tissue, visual inspection, fatigue testing, and function testing. Performance testing shows the reprocessed sealer/dividers to perform as intended. |
| **Conclusion:** | The reprocessed sealer/divider is substantially equivalent to the Covidien LigaSure Impact™ Hand Activated Sealer/Divider (K070162). This conclusion is based upon the devices' similarities in functional design (principles of operation), materials, indications for use and methods of construction. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 5 2012

SterilMed, Incorporated
% Mr. Jason Skramsted
Regulatory Affairs Specialist
11400 73rd Avenue North
Maple Grove, Minnesota 55369

Re: K120040
Trade Name: Reprocessed Surgical Electric Instrument
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: NUJ
Dated: September 28, 2012
Received: October 2, 2012

Dear Mr. Skramsted:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known):

Device Name: Reprocessed Surgical Electric Instrument

Indications for Use:

The Reprocessed Surgical Electric Instrument (hereinafter sealer/divider) is indicated for use in open surgical procedures to seal vessels up to and including 7 mm, lymphatics, and tissue bundles. When used with the ForceTriad™ energy platform the sealer/divider can also be used to seal pulmonary vasculature. The sealer/divider should not be used for tubal sterilization or tubal coagulation as it has not been shown effective for sterilization procedures.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120040